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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,035

06/25/2003

Clarence Nathaniel Ahlem

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06/01/2006

HOLLIS-EDEN PHARMACEUTICALS, INC.

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/607,035	Applicant(s) AHLEM ET AL.	
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50 and 54-84 is/are pending in the application.
 4a) Of the above claim(s) 56,60,65 and 68-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 50,54,55,57-59,61-64,66,67 and 77-84 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/1/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

First Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 50 and 54-84 are pending in the present application. Claims 56, 60, 65 and 68-76 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 50, 54, 55, 57-59, 61-64, 66, 67 and 77-84 will be examined to the extent they read on the elected species according to MPEP § 803.02.

Election/Restrictions

3. Applicant's amendment to claim 50 is noted. However, said amendment does not fully respond to the restriction requirement. For the record, only compounds wherein R⁸ is -CH₂- will be examined in the present application.

Applicant's request for a list of inventions is noted. It is suggested that the definition of R⁸ in the present application be limited to one of the three definitions in each case because said would change the classification of the claimed invention.

Specification

4. The disclosure is objected to because of the following informalities: Missing data and overlapping structures (see for example pages 89, 115, 137, 211 and 239).

Appropriate correction is required.

Claim Objections

5. Claims 66 and 67 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claims recite several compounds, for example, 3 β ,7 β ,16 α ,17 β -tetrahydroxyandrost-5-ene, not encompassed by parent claim 62.

Double Patenting

6. The provisional rejection of claims 50, 55, 57, 59, 61, 62, 64, 66 and 77-84 over claims of copending Application No. 10/728,400 is withdrawn.

7. The provisional rejections of (a) claims 50, 57, 61, 62 and 77-84 under the judicially created doctrine of obviousness-type double patenting over claims 20-22 of copending Application No. 10/607,415 and (b) claims 50, 57, 61, 62, 66 and 77-84 under the judicially created doctrine of obviousness-type double patenting over claims 1-17 of copending Application No. 10/949,694 are maintained and claims 66 and 67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims of copending Application Nos. 10/607,415 and 10/949,694.

Applicant's statement that the provisional rejections be held in abeyance is noted.

Claim Rejections - 35 USC § 103

8. The rejection of claims 50, 55, 57 and 59 under 35 USC 103(a) over Daynes et al. (US 5,532,230) is withdrawn.

9. Claims 50, 54, 55, 57-59, 61-64, 66, 67 and 77-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowell et al. (US 5,859,000).

Dowell et al. teaches reduction of mast cell mediated allergic reaction, including asthma, by administering a dehydroepiandrosterone derivative (see the entire article, especially Abstract; col. 6, line 66 – col. 7, line 5; col. 8, line – col. 14, line 20).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. For example, the instant claims recite compounds wherein R¹ and R³ are hydroxyl groups. However, the reference teaches (a) compounds such as 16 α -hydroxy-5-androsten-17 α -ol, 16 α -methyl-16 β -fluoro-5 α -androsten-17 α -ol and 3 α -ethoxy-5 α -androstan-17 β -ol (see col. 12, line 15 – col. 13, line 13) and (b) an equivalent between several groups, including those recited by the instant claims, in the 3- and 16-positions of the steroid moiety. Therefore, modification of the exemplified prior art compounds, for example 3 α -ethoxy-5 α -androstan-17 β -ol by addition of a hydroxyl group in the 16-position or 16 α -hydroxy-5-androsten-17 α -ol by addition of –OH, –SH, an ester or ether group in the 3-position, would be obvious to the

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skilled artisan in the art because he would have the reasonable expectation that the compound(s) obtained would be useful in reducing mast cell mediated allergic reaction as taught by the reference. The motivation is based on the teaching of equivalence of said groups in these positions (see col. 8, lines 40-47 and 65-67) and the desire to make additional compounds as taught by the reference for reduction of mast cell mediated allergic reaction.

Response to Arguments

10. Applicant's response and the declaration filed April 25, 2006 are noted. The examiner notes the data in the declaration does not include a comparison between the $3\beta,16\alpha$ -dihydroxy-17oxoandrostane and the corresponding $3\beta,16\alpha,17$ -trihydroxyandrostane. For a showing of unexpected and unobvious results comparison has to be made between the closest prior art compound and the corresponding claimed compound which differs from said prior art compound in one position not two or three positions as shown by applicant's declaration.

However, the 103 rejection over US patent No. 5,532,230 has been withdrawn as indicated over in #8 above. The rejection was withdrawn based on applicant's argument that the prior art excludes the claimed compounds.

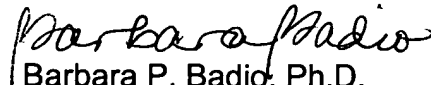
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Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB

May 30, 2006